technician, and to facilitate transport of said recording device to a processing facility by a common courier.

C1 cont'd

27. (Amended) An assessment device according to claim 20 wherein said assay part [is characterized by] comprises multiple sample application wells.

C2

34. (Amended) An assessment device according to claim 33 wherein said primary conduit contains at least one assay reagent, and wherein said assay reagents of said secondary conduit are of a different nature [to the] than said at least one assay reagent in [the] said primary conduit.

C3

REMARKS

Reconsideration and allowance of this application are respectfully requested in light of the above amendments and the following remarks. Entry of the instant amendment is respectfully requested.

Claims 20, 21, 27 and 34 have been amended hereby. Particularly, claim 20 has been amended to clarify that the recording part only records the assay information without analyzation thereof, and support in the specification is found at least at page 13, second paragraph). Claims 21 and 34 have been amended to overcome rejection under 35 U.S.C. §112, second

paragraph, by removing the phrase "small and light" from claim 21, and by introducing proper antecedent basis to the elements recited in claim 34. Claim 27 has been amended to improve its form.

Grounds of Final Rejection

I. Claims 21, 29 and 34 stand rejected under 35 U.S.C. §112, second paragraph.

It is respectfully submitted that this rejection is traversed for the reasons indicated herein below.

With regard to the rejection of claim 21, the Final Rejection alleges that the phrase "small and light" is allegedly a relative term as to what can be considered small and light.

In response, Applicant has amended claim 21 to recite that the detachable recording part is "sized to facilitate personal handling by one of said user and a technician, and to facilitate transport of said recording device to a processing facility by a common courier." Support for this change is found in the specification at least at page 4, lines 1-3, and page 12, line 24 to page 13, line 3.

With regard to the rejection of claim 29, the Final Rejection alleges that it is not clear from the specification what are the reagents for diluting said sample fluid.

In response, it is respectfully submitted that the specification discloses at page 6, lines 3-4, and page 9, lines 3-4, that the primary conduit may contain assay reagents suitable for diluting the sample fluid. In addition, the specification discloses that the assay reagents may comprise (by example and not by way of limitation) buffers (please see the specification at page 7, lines 14-15). It is respectfully submitted that a person of ordinary skill in the art would understand that the use of a buffering assay reagent would dilute the sample fluid.

With regard to the rejection of claim 34, the Final Rejection alleges that the assay reagents lack antecedent basis.

In response, claim 34 has been amended to recite that "said primary conduit contains at least one assay reagent, and wherein said assay reagents of said secondary conduit are of a different nature than said at least one assay reagent in said primary conduit."

It is respectfully submitted that the above changes to claim 34 overcomes the rejection under 35 U.S.C.§112, second paragraph.

Accordingly, it is respectfully submitted that all grounds of rejection under 35 U.S.C. §112, second paragraph, have been overcome.

II. Claims 20-39 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Chow (U.S. 5,955,028, hereinafter "Chow").

It is respectfully submitted that this rejection should be withdrawn.

According to the Final Rejection, Chow allegedly discloses a base unit for interfacing an assay substrate with a recording device. The assay substrate comprises a plurality of sample and reagent wells connected with micro channels (See column 11, line 48 to column 12, line 6; and Fig. 1) Chow allegedly discloses an assay substrate that is removable from a recording part.

In response, it is respectfully submitted that none of the present claims are anticipated by Chow. By way of example, the following explanation is provided regarding the medical assay process to highlight the patentable features of the Applicants' claims.

There are a series of steps which take a patient from obtaining a sample to providing a diagnosis. These steps can be summarized as follows:

1). Obtaining a fluid sample for analysis;

2). Carrying out an assay procedure on the said sample;

3). Obtaining and recording the results of the assay procedure (i.e. the raw assay data);

4). Processing the raw data (e.g. against a set of pre-determined standards) to determine the medical significance thereof; and

5). Producing a diagnosis on the basis of the medically analyzed data.

The patentability of the presently claimed invention lies in steps 1-4, or 2-4. The sample (step 1) may be obtained by a clinician, or by the patient itself.

The presently claim invention carries out the assay procedure on the sample, and the obtaining and recording of *the results* the assay procedure. The presently claimed invention recites an assay part and a recording part, with the recording part being detachable from the assay part.

After the assay is performed by the assay part, claim 20 recites that the recording part records the data "without analyzation thereof in a form suitable for onward transmission for subsequent processing and analysis at a remote data processing site."

The detachable recording part records the assay information, and the recording part can be detached from the assay part and sent

to a remote site for analysis. The advantages of such a device include: 1) better accessibility for patients living remote to diagnostic centers to receive fast and accurate diagnosis; 2) reduced costs of transport because only the recording device is sent to the remote center for processing, instead of the entire device; 3) better integrity of the results because the user cannot manipulate the raw data contained in the recording part; 4) confidentiality is improved because the raw data, not the diagnosis, is being forwarded to the remote site; and 5) better safety procedures result because the invention reduces the risk of exposure of lab personnel to potential illnesses (e.g. H.I.V., Ebola, bovine spongiform encephalopathy to name a few) because the sample is not transported.

In contrast, Chow fails to disclose or suggest providing raw data in the form of a detachable recording part to a remote data processing site for analysis. Chow merely uses a base unit, either integrally or in combination with a computer, to perform the obtaining and recording of the results and the processing of the raw data.

It is respectfully submitted that Chow is completely silent regarding that an assay part performs an assay, and that a detachable recording part only records the assay information

without analyzation thereof, for subsequent transmission of the raw data to a remote data processing site for analysis, as recited by the Applicant.

Chow envisages performing the entire analysis locally in a conventional manner, which fails to achieve the distinct advantages of the present invention. For example, there is the need in the device disclosed by Chow to provide potentially complex data collection and analysis (e.g. computer and software) *locally*, along with the essay equipment at the site where the assay is performed.

It is clear that the costs involved preempt the device disclosed by Chow from anticipating an inexpensive, light-weight system which can be shipped virtually anywhere in the world where medical care is impeded by the inability of patients to travel to medical testing centers, or the lack of such centers at reasonable distances from the residence of such patients.

For all the foregoing reasons, it is respectfully submitted that the ground of rejection under 35 U.S.C.§102(e) is overcome. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

III. Claims 20-39 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Hillman et al (U.S. 4,756,884 and 4,963,498 hereinafter referred to as "Hillman '884" and "Hillman

'498" respectively) in view of either Galen et al. (U.S. 5,695,949 hereinafter "Galen") of Phillips et al. (U.S. 5,179,005 and 5,426,032, hereinafter "Phillips '005" and "Phillips '032" respectively).

The Final Rejection incorporates by the reference the same rejection in the Office Action mailed February 9, 2000.

In response, it is respectfully submitted that the combination of applied references fails to disclose or suggest a an assessment device having an assay part and a detachable recording part, said recording part being in data communication with the assay part to receive assay information, and then being detached from the assay part for analyzation of the assay information at a remote data processing site.

Galen and Phillips disclose a microprocessor. In neither case is the microprocessor of Galen or Phillips can be said to be detachable recording parts. Moreover, in neither case is the microprocessor ever attached to the assay part to collect the data, then detached to be sent to a remote data processing site for analysis.

Moreover, the Applicant's claims do not recite a microprocessor, but instead recite a detachable recording part for the storage of assay information, wherein the recording part only

records the said assay information without analyzation thereof in a form suitable for onward transmission for subsequent processing and analysis. As indicated above in the traversal regarding Chow, the instant invention has distinct advantages from only having the recording part analyzed, which include, privacy, safety, integrity of results, greater accessibility due to reduce shipment costs, no need for local testing centers, etc.

It is respectfully submitted that the combination of references fails to disclose, suggest, or provide motivation to a person of ordinary skill in the art that would have made the instant claims obvious in view thereof. Nor does the combination of references suggest or provide motivation to provide the advantages of the structure of the presently claimed invention.

In light of the foregoing, it is respectfully submitted that the present application is in condition for allowance, and a notice to that effect is respectfully solicited.

If any issues remain which may best be resolved through a telephone communication, the Examiner is requested to kindly telephone the undersigned at the local Washington, DC telephone number listed below.

AMENDMENT AFTER FINAL REJECTION
U.S. Appln. No. 09/381,561

Respectfully submitted,

Date: February 5, 2001

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